

PROTOCOL OUTLINE

PROTOCOL NUMBER: WHOTI G-040

PROTOCOL TITLE:

***Effect of Frequent Daily Use for Four Weeks of a MICRODENT® - containing, Sorbitol-based, Chewing Gum in Reducing Dental Plaque Accumulation When Compared to a Placebo Gum and A No-Chewing Control Period:
A Double Blind, Crossover Treatment Design***

PRINCIPLE INVESTIGATOR: Thomas Schiff, D.M.D.
CLINICAL TRIAL SITE: Univ. of the Pacific School of Dentistry
TECHNICAL SPONSOR: Ira Hill, Ph.D., WhiteHill Oral Technologies, Inc.
LICENSEE SPONSOR: Richard Peck, President, Ranir-DCP, West Orange, NJ
GUM MANUFACTURER: Gary Kehoe, President, Gum Tech, Inc., Phoenix, AZ

Subjects: 20 to finish

Product Use Instructions:

Chew two pieces of the assigned chewing gum for 20 minutes after each meal [3X Daily].

Oral Hygiene Instructions:

Subjects are to follow their normal and customary tooth brushing habits, using the same toothbrush and toothpaste as they normally do.

Subjects are not to use any mouthwash, mints or chewing gums except those provided for the study.

Last tooth brushing before reporting to the clinic for each plaque examination is to be the evening before (12 hour plaque regrowth).

DAY 1 Subjects scored for Plaque (Baseline)
 Expanded Turesky Modification of Quigley-Hein (Shaver-Schiff)
 Soft Tissue Assessment Recorded
 Rubber Cup prophylaxis to reduce plaque scores to zero.
 Assign one-half the subjects Gum # 050, the other half Gum # 315
 Instruct Subjects on Product Use and Oral Hygiene Instructions
 Provide Assigned Product for One Month's Use.

DAY 28 Subjects scored for Plaque (Final)
 Record Soft Tissue Assessment, noting any treatment related changes
 Rubber Cup prophylaxis to zero
 Supply sugar-free breath mints for the "No-Chewing Gum Control" period.

